FOI 24/130 - 150 Day Assessment for National Applications for Medicines

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Fri 23/02/2024 14:37

To: [redacted]

FOI 24/130

Dear [redacted]

Regarding your request for information that was submitted on 26 January 2024, please see below our response to each of your questions below:

1. **What does it mean for a MAA to be validated?**

All submissions for Marketing Authorisation Applications (MAAs) are validated before the start of assessment. This means that each application will be checked to make sure that the MAA form has been completed correctly (including the legal basis), and the correct documentation and fees have been provided.

2. **Is this simply a receipt of submission of a MAA or more thorough check that takes days/weeks?**

Applications are validated by MHRA within 2 weeks of receipt of an application. However, this timeline does not include time taken to sort through issues with applicants to prevent the invalidation of an application.

3. **Is there any way for the public to know when a MAA has been validated?**

MHRA does not publish any information on applications that are currently pending. This includes publishing when pending MAAs have been validated.

4. **When does the official time clock start for assessment? On submission, or validation?**

The official clock time for the start of an assessment is on validation of an application.

5. **How does the CHM meeting fit into the timeline? Does phase 1 need to be complete for the meeting to occur? Does the CHM meeting need to have occured for phase 2 to begin? Or is it completely independent?**

Applications can be taken to the Commission of Human Medicines (CHM) after Phase 1 or Phase 2 of assessment.

6. **How does a group like the Cancer Vaccines Expert Working Group fit in to the assessment?**

The Cancer Vaccines Expert Working Group is not currently involved in the assessment of MAAs. This group is supporting the Agency to examine whether the regulatory framework in place is able to support assessment of personalised cancer vaccines products that are in early stages of development**.**

7. **For all the questions above, I am specifically interested in the submission made by Northwest Biotherapeutics on December 20th for their MAA for DCVAX-L. If you could shed any light on the process and where they may be within it would be very helpful**.

We are aware of the following post that has been made by Northwest Biotherapeutics:

https://nwbio.com/northwest-biotherapeutics-announces-marketing-authorization-applications-submitted-uk-mhra-dcvax-l-glioblastoma/

Any further information on this application would be exempt under Section 41(1) and Section 43(2) of the Freedom of Information (FOI) Act.

41.—(1) Information is exempt information if —

(a) it was obtained by the public authority from any other person (including another public authority), and,

(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

43.

(1)Information is exempt information if it constitutes a trade secret.

(2)Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

(3)The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the provision of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in refusing outweighs the public interest in providing any information we hold. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in releasing further information on this issue. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of providing information

To provide information on an application received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see what applications are currently being considered by MHRA.

Considerations in favour of refusing to provide information

To provide further information on an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA and how it is being assessed/where it is in the assessment process can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to provide information on applications that are not yet authorised in the UK can create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

If you have a query about the information provided, please reply to this email

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind

that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Yours sincerely,

MHRA Customer Experience Centre

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

From: [redacted]
Sent: Friday, January 26, 2024 6:24 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: 150 Day Assessment for National Applications for Medicines

Hello,

I had a few questions regarding the assessment pathway noted in the subject line.

1. What does it mean for a MAA to be validated?

2. Is this simply a receipt of submission of a MAA or more thorough check that takes days/weeks?